IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kenneth F. Buechler

Title: DIAGNOSTIC DEVICES AND APPARATUS FOR THE CONTROLLED MOVEMENT OF REAGENTS WITHOUT MEMBRANES

Prior Appl. No.: 09/613,650

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Examiner: Unassigned

Art Unit: 1641

CERTIFICATE OF EXPRESS MAILING

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(Signature)

PRELIMINARY AMENDMENT

Commissioner for Patents
Box PATENT APPLICATION
Washington, D.C. 20231

Sir:

Prior to examination of the present Continuing Application, Applicant respectfully requests that the application be amended as follows:

In the Specification:

Please replace page 1, line 4, with the following:

-- This application is a continuation of Application No. 09/613,650, filed July 10, 2000, which is a continuation-in-part of U.S. Patent Application No. --

The following shows the amendments made to the first line in marked-up form:

-- This application is a continuation of Application No. 09/613,650, filed July 10, 2000, which is a continuation-in-part of U.S. Patent Application No. --

In the Claims:

Please cancel claims 1-73 and add new claims 74-100 as follows:

74. (New) An assay device for determining the presence or amount of a plurality of target ligands in a sample, the device comprising:

a diagnostic element comprising a capillary space through which said sample flows, comprising (i) a non-absorbent surface within said capillary space, and (ii) a plurality of discrete capture zones on said nonabsorbent surface, each discrete capture zone comprising a capture element that binds one target ligand in said plurality of target ligands.

75. (New) The assay device of claim 74, comprising at least 50 said discrete capture zones, corresponding to at least 50 target ligands.

76. (New) The assay device of claim 74, wherein said nonabsorbent surface comprises a width dimension substantially perpendicular to the direction of fluid flow through the capillary space, and wherein each said discrete capture zone spans said width dimension.

77. (New) The assay device of claim 74, wherein said capture element is selected from the group consisting of an antibody or binding fragment thereof, a nucleotide sequence, an enzyme, a chelator, and a biosensor.

78. (New) The assay device of claim 74, wherein said device further comprises a chamber fluidly connected to said diagnostic element, and a time gate that delays fluid flow between said chamber and said diagnostic element.

79. (New) The assay device of claim 74, wherein said discrete capture zones comprise particles immobilized thereon, wherein said particles comprise said capture element immobilized thereon.

80. (New) The device of claim 79 wherein the particles are latex.

81. (New) The device of claim 79 wherein the particles are polystyrene.

82. (New) The device of claim 79 wherein the particles are nanoparticles.

83. (New) The device of claim 82 wherein the nanoparticles comprise silica, zirconia, alumina, titania, ceria, metal sols, or polystyrene.

84. (New) The device of claim 82 wherein the nanoparticles have sizes in a range from about 1 nm to 100 nm.

85. (New) The device of claim 82 wherein the nanoparticles are immobilized on said nonabsorbent surface through adsorption or covalent bonds.

86. (New) The device of claim 79 wherein said particles are immobilized on said nonabsorbent surface by magnetic means, hydrophobic means, hydrogen bonding, electrostatic means, or entrapment.

87. (New) The device of claim 79, wherein said particles have diameters ranging from about 0.1 mm to 10 mm.

88. (New) The device of claim 79, wherein said receptor is immobilized on a surface of the particle.

89. (New) A method for determining the presence or amount of a plurality of target ligands in a sample, the method comprising:

contacting the diagnostic element of claim 1 with

(i) a sample, and

(ii) a labeled reagent that binds to said plurality of target ligands,

whereby said sample and said labeled reagent flow through said capillary space for capture of each said target ligand at its corresponding capture zone; and

generating a plurality of detectable signals from label bound to each target ligand at its corresponding capture zone, whereby said signals are related to the presence or amount of said plurality of target ligands in said sample.

90. (New) The method of claim 89, wherein said diagnostic element comprises at least 50 said discrete capture zones, corresponding to at least 50 target ligands.

91. (New) The method of claim 89, wherein said nonabsorbent surface comprises a width dimension substantially perpendicular to the direction of fluid flow

through the capillary space, and wherein each said discrete capture zone spans said width dimension.

92. (New) The method of claim 89, wherein said capture element is selected from the group consisting of an antibody or binding fragment thereof, a nucleotide sequence, an enzyme, a chelator, and a biosensor.

93. (New) The method of claim 89, wherein said discrete capture zones comprise particles immobilized thereon, wherein said particles comprise said capture element immobilized thereon.

94. (New) The method of claim 89, wherein said labeled reagent is a fluorescently labeled reagent.

95. (New) A method for determining the presence or amount of a plurality of target ligands in a sample, the method comprising:

contacting the diagnostic element of claim 1 with

(i) a sample, and

(ii) a plurality of ligand analogue conjugates, each ligand analogue conjugate corresponding to one of said plurality of target ligands,

whereby said sample and said plurality of ligand analogue conjugates flow through said capillary space, whereby each target ligand competes with its corresponding ligand analogue conjugate for capture at its corresponding capture zone; and

generating a plurality of detectable signals from ligand analogue conjugate bound at its corresponding capture zone, whereby said signals are related to the presence or amount of said plurality of target ligands in said sample.

96. (New) The method of claim 95, wherein said diagnostic element comprises at least 50 said discrete capture zones, corresponding to at least 50 target ligands.

97. (New) The method of claim 95, wherein said nonabsorbent surface comprises a width dimension substantially perpendicular to the direction of fluid flow through the capillary space, and wherein each said discrete capture zone spans said width dimension.

98. (New) The method of claim 95, wherein said capture element is selected from the group consisting of an antibody or binding fragment thereof, a nucleotide sequence, an enzyme, a chelator, and a biosensor.

99. (New) The method of claim 95, wherein said discrete capture zones comprise particles immobilized thereon, wherein said particles comprise said capture element immobilized thereon.

100. (New) The method of claim 95, wherein said ligand analogue conjugate is a fluorescently labeled ligand analogue conjugate.

REMARKS

Applicant respectfully requests that the foregoing amendments be made prior to examination of the present application. These amendments are fully supported by the specification as filed, and do not present new matter. For example, the diagnostic element of the presently claimed devices are described, *e.g.*, beginning on page 25, line 1; Diagnostic elements comprising at least 50 discrete capture zones are described, *e.g.*, in figures 3A and 3B; and capture zones that span the entire width dimension of a capillary space are described, *e.g.*, in figure 3A. Moreover, methods for using the claimed assay devices are described, *e.g.*, beginning on page 36, line 23.

Applicant believes that the present application is now in condition for allowance. Favorable consideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date March 13, 2001

By [signature]

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